

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No
0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
93-R-0449

CUSTOMER NO.
11593

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

AVANIR PHARMACEUTICALS
11388 SORRENTO VALLEY ROAD(b)(2)High, (b)(7)(F)
SAN DIEGO, CA 92121

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	1			169	169
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

11/07/2005

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (Oct 88), which is obsolete)

PART 1 - HEADQUARTERS

1. Registration Number: 93-R-0449 / 11593

2/3. Species (common name) & Number of animals used in this study:

Guinea Pigs (169)

4. Explain the procedure producing pain and/or distress.

I. Female Hartley guinea pigs are inoculated intravaginally with HSV-2, which will produce virus-induced lesions. The inoculation is accomplished using a moistened cotton swab soaked in an appropriate virus concentration. The swab is inserted into the vaginal tract rupturing the vaginal closure membrane and it is rotated approximately 10 times. Topical treatment is given three times daily beginning 24 hours after viral inoculation and is continued for 10-11 days. Topical treatment will be applied using a cotton swab both intravaginally and topically to the perineal skin of the guinea pig. II. Female IAF HA/HO (Hairless) and Hartley guinea pigs are inoculated with HSV-2, which will produce virus-induced lesions, by placing the viral inoculum in the center of the skin site, inserting a tattoo needle into the pool of virus, and inoculating by drawing the electrically activated needle away from the virus pool in six different directions. This results in six lines radiating away from the center of the inoculation site with discrete vesicles that can be counted. Treatment is initiated two hours after inoculation by topically applying a cream with a glass rod using gentle circular rubbing. The animals will be treated 3-5 times per day for 4-6 days.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

I and II. During all procedures the guinea pigs are anesthetized using inhaled isoflurane to minimize both pain and stress. Topical analgesics cannot be used on the virus-induced lesions without compromising the results of the study, since topical treatments themselves are being investigated. Systemic analgesics such as NSAIDS or narcotic analgesics have effects on the immune system and would not be appropriate for use in these studies because they will affect the immune system; which will then affect the reaction to the virus.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: None

CFR:

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason: